

1 KAMALA D. HARRIS
Attorney General of California
2 JANICE K. LACHMAN
Supervising Deputy Attorney General
3 JEFFREY M. PHILLIPS
Deputy Attorney General
4 State Bar No. 154990
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 324-6292
Facsimile: (916) 327-8643
7 *Attorneys for Complainant*

8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 5707

12 **FRESNO PHARMACY**
13 **QUI VAN LY, OWNER**
14 **4917 E. Kings Canyon Road, No. 102**
15 **Fresno, CA 93727**

A C C U S A T I O N

16 **Pharmacy Permit No. PHY44487**

17 **QUI VAN LY**
18 **4716 W. Alluvial Avenue**
19 **Fresno, CA 93722**

20 **Pharmacist License No. RPH 41386**

21 Respondents.

22 Virginia Herold ("Complainant") alleges:

23 **PARTIES**

24 1. Complainant brings this Accusation solely in her official capacity as the Executive
25 Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.

26 **Original Pharmacy Permit**

27 2. On or about November 19, 1999, the Board issued Original Pharmacy Permit Number
28 PHY 44487 to Qui Van Ly ("Respondent"), doing business as Fresno Pharmacy, with
Respondent as the Pharmacist-in-Charge. The Original Pharmacy Permit was in full force and

1 effect at all times relevant to the charges brought herein and will expire on November 1, 2016,
2 unless renewed.

3 **Original Pharmacist License**

4 3. On or about October 16, 1987, the Board issued Original Pharmacist License Number
5 RPH 41386 to Respondent. The Original Pharmacist License was in full force and effect at all
6 times relevant to the charges brought herein and will expire on February 28, 2017, unless
7 renewed.

8 **JURISDICTION**

9 4. This Accusation is brought before the Board under the authority of the following
10 laws. All section references are to the Business and Professions Code (the "Code") unless
11 otherwise indicated.

12 5. Code section 4300 states, in pertinent part:

13 (a) Every license issued may be suspended or revoked.

14 (b) The board shall discipline the holder of any license issued by the board,
15 whose default has been entered or whose case has been heard by the board and found
guilty, by any of the following methods:

16 (1) Suspending judgment.

17 (2) Placing him or her upon probation.

18 (3) Suspending his or her right to practice for a period not exceeding one year.

19 (4) Revoking his or her license.

20 (5) Taking any other action in relation to disciplining him or her as the board in
21 its discretion may deem proper . . .

22 6. Code section 4300.1 states:

23 The expiration, cancellation, forfeiture, or suspension of a board-issued license
24 by operation of law or by order or decision of the board or a court of law, the
placement of a license on a retired status, or the voluntary surrender of a license by a
25 licensee shall not deprive the board of jurisdiction to commence or proceed with any
investigation of, or action or disciplinary proceeding against, the licensee or to render
26 a decision suspending or revoking the license.

26 ///

27 ///

28 ///

1 11. Code section 4125(a) states:

2 Every pharmacy shall establish a quality assurance program that shall, at a
3 minimum, document medication errors attributable, in whole or in part, to the
4 pharmacy or its personnel. The purpose of the quality assurance program shall be to
5 assess errors that occur in the pharmacy in dispensing or furnishing prescription
6 medications so that the pharmacy may take appropriate action to prevent a recurrence.

6 12. Section 4307(a) of the Code states that:

7 Any person who has been denied a license or whose license has been revoked or
8 is under suspension, or who has failed to renew his or her license while it was under
9 suspension, or who has been a manager, administrator, owner member, officer,
10 director, associate, or partner of any partnership, corporation, firm, or association
11 whose application for a license has been denied or revoked, is under suspension or
12 has been placed on probation, and while acting as the manger, administrator, owner,
13 member, officer, director, associate, or partner had knowledge or knowingly
14 participated in any conduct for which the license was denied, revoked, suspended, or
15 placed on probation, shall be prohibited from serving as a manger, administrator,
16 owner, member, officer, director, associate, or partner of a licensee as follows:

12 (1) Where a probationary license is issued or where an existing license is placed
13 on probation, this prohibition shall remain in effect for a period not to exceed five
14 years.

14 (2) Where the license is denied or revoked, the prohibition shall continue until
15 the license is issued or reinstated.

16 13. Health and Safety Code section 11165(d) states:

17 For each prescription for a Schedule II, Schedule III, or Schedule IV controlled
18 substance, as defined in the controlled substances schedules in federal law and
19 regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of
20 Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other
21 dispenser shall report the following information to the Department of Justice as soon
22 as reasonably possible, but not more than seven days after the date a controlled
23 substance is dispensed, in a format specified by the Department of Justice:

21 (1) Full name, address, and, if available, telephone number of the ultimate user
22 or research subject, or contact information as determined by the Secretary of the
23 United States Department of Health and Human Services, and the gender, and date of
24 birth of the ultimate user.

24 (2) The prescriber's category of licensure, license number, national provider
25 identifier (NPI) number, if applicable, the federal controlled substance registration
26 number, and the state medical license number of any prescriber using the federal
27 controlled substance registration number of a government-exempt facility.

26 (3) Pharmacy prescription number, license number, NPI number, and federal
27 controlled substance registration number.

28 (4) National Drug Code (NDC) number of the controlled substance dispensed.

1 (5) Quantity of the controlled substance dispensed.

2 (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or
3 10th revision (ICD-10) Code, if available.

4 (7) Number of refills ordered.

5 (8) Whether the drug was dispensed as a refill of a prescription or as a first-
6 time request.

7 (9) Date of origin of the prescription.

8 (10) Date of dispensing of the prescription.

9 14. California Code of Regulations, title 16 ("Regulations"), section 1716, states, in
10 pertinent part:

11 Pharmacists shall not deviate from the requirements of a prescription except
12 upon the prior consent of the prescriber or to select the drug product in accordance
13 with Section 4073 of the Business and Professions Code.

14 15. Regulations, section 1717(d), states:

15 Each pharmacy shall use the findings of its quality assurance program to
16 develop pharmacy systems and workflow processes designed to prevent medication
17 errors. An investigation of each medication error shall commence as soon as is
18 reasonably possible, but no later than 2 business days from the date the medication
19 error is discovered. All medication errors discovered shall be subject to a quality
20 assurance review.

21 16. Regulations, section 1718, states:

22 "Current Inventory" as used in Sections 4081 and 4332 of the Business and
23 Professions Code shall be considered to include complete accountability for all
24 dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

25 The controlled substances inventories required by Title 21, CFR, Section 1304
26 shall be available for inspection upon request for at least 3 years after the date of the
27 inventory.

28 17. Code of Federal Regulations, title 21, section 1304.11, states, in pertinent part:

(a) General requirements. Each inventory shall contain a complete and accurate
record of all controlled substances on hand on the date the inventory is taken, and
shall be maintained in written, typewritten, or printed form at the registered location.
An inventory taken by use of an oral recording device must be promptly transcribed.
Controlled substances shall be deemed to be "on hand" if they are in the possession of
or under the control of the registrant, including substances returned by a customer,
ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the
registrant, and substances in the possession of employees of the registrant and
intended for distribution as complimentary samples. A separate inventory shall be
made for each registered location and each independent activity registered, except as

1 provided in paragraph (e)(4) of this section. In the event controlled substances in the
2 possession or under the control of the registrant are stored at a location for which
3 he/she is not registered, the substances shall be included in the inventory of the
4 registered location to which they are subject to control or to which the person
5 possessing the substance is responsible. The inventory may be taken either as of
6 opening of business or as of the close of business on the inventory date and it shall be
7 indicated on the inventory.

8 (c) Biennial inventory date. After the initial inventory is taken, the registrant
9 shall take a new inventory of all stocks of controlled substances on hand at least every
10 two years. The biennial inventory may be taken on any date which is within two years
11 of the previous biennial inventory date.

12 COST RECOVERY

13 18. Code section 125.3 provides, in pertinent part, that a Board may request the
14 administrative law judge to direct a licensee found to have committed a violation or violations of
15 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
16 enforcement of the case.

17 DRUGS

18 19. "Metformin hydrochloride", used in the management of diabetes, is a dangerous drug
19 within the meaning of Code section 4022.

20 20. "Soma" is the brand name for Carisoprodol, a dangerous drug within the meaning of
21 Code section 4022, and a controlled substance as defined by the Code of Federal Regulations,
22 title 21, section 1308.14(c)(6).

23 BACKGROUND

24 21. On or about February 10, 2015, "T.M.", a health care provider, issued a prescription
25 to "T.M.M.," for 40 tabs of 350 mg. of Soma (Carisoprodol). T.M.M.'s prescription was filled
26 that same day by Respondent. T.M.M. took the medication dispensed by Respondent and
27 subsequently suffered nausea, vomiting and diarrhea. On or about March 19, 2015, T.M.M.
28 returned to T.M., who determined that Respondent furnished Metformin to T.M.M. instead of
Soma (Carisoprodol).

22. On or about June 10, 2015, a Board Inspector conducted an inspection of Respondent
Fresno Pharmacy in response to a complaint it received from T.M.M. The investigator found that
Respondent did not have a Quality Assurance Program in place, did not have a Biennial Inventory

1 of controlled substances, and had not transmitted data to CURES since 2012. The investigator
2 further confirmed that Respondent furnished Metformin instead of Carisoprodol to T.M.M. and
3 that Respondent had not documented or investigated the medication error.

4 **FIRST CAUSE FOR DISCIPLINE**

5 (Code Violations Governing Pharmacy)

6 23. Respondent's pharmacy permit and pharmacist license is subject to disciplinary
7 action pursuant to Code section 4301(o), for unprofessional conduct, in that Respondent violated
8 or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired
9 to violate, the Pharmacy Law (Code section 4000, et seq.), as follows:

10 a. **Code section 4125(a)**: Respondent did not have a *Quality Assurance Program*, as
11 required.

12 b. **Health and Safety Code Section 11165(d)**: As of June 10, 2015, Respondent failed
13 to report to the Department of Justice through CURES controlled substances it had dispensed
14 since in or around 2012.

15 **SECOND CAUSE FOR DISCIPLINE**

16 (Violations of Federal and State Regulations Governing Pharmacy)

17 24. Respondent's pharmacy permit and pharmacist license is subject to disciplinary
18 action pursuant to Code section 4301(o), for unprofessional conduct, in that Respondent violated
19 or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired
20 to violate regulations governing pharmacy, as follows:

21 a. **Regulation, Section 1716**: On or about February 10, 2015, Respondent dispensed
22 metformin to T.M.M. in place of Carisoprodol.

23 b. **Regulation, Section 1711(d)**: Respondent failed to, within two business days of
24 discovery, document or investigate the medication error that occurred on or about February 10,
25 2015, when Respondent dispensed metformin to T.M.M. in place of Carisoprodol.

26 c. **Code of Federal Regulations, Title 21, Section 1304.11(a)&(c)**: As of on or about
27 June 10, 2015, Respondent failed to maintain a biennial inventory of controlled substances.

28 //

1 e. **Regulation section 1718:** On or about June 10, 2015, Respondent did not have a
2 controlled substances inventory available for inspection for at least three years prior.

3 **OTHER MATTERS**

4 25. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
5 PHY44487 issued to Fresno Pharmacy, then Fresno Pharmacy shall be prohibited from serving as
6 a manger, administrator, owner, member, officer, director, associate, or partner of a licensee for a
7 period not to exceed five years if Pharmacy Permit Number PHY44487 is placed on probation or
8 until Pharmacy Permit Number PHY44487 is reinstated, if the permit is revoked.

9 26. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
10 PHY44487 issued to Fresno Pharmacy or if discipline is imposed on Pharmacist License No.
11 RPH 41386 issued to Qui Van Ly, for violations during the time that Qui Van Ly acted as a
12 manger, administrator, owner, member, officer, director, associate, or partner and Qui Van Ly
13 had knowledge or knowingly participated in any conduct for which the permit or license was
14 disciplined, then Qui Van Ly shall be prohibited from serving as a manger, administrator, owner,
15 member, officer, director, associate, or partner on a license or permit issued by the Board for a
16 period not to exceed five years if discipline results in probation or until the license or permit is
17 reinstated, if the license or permit is revoked.

18 **PRAYER**

19 **WHEREFORE,** Complainant requests that a hearing be held on the matters herein alleged,
20 and that following the hearing, the Board of Pharmacy issue a decision:

21 1. Revoking or suspending Original Pharmacy Permit Number PHY 44487, issued to
22 Qui Van Ly, doing business as Fresno Pharmacy;

23 2. Revoking or suspending Original Pharmacist License Number RPH 41386, issued to
24 Qui Van Ly;

25 3. Prohibiting Fresno Pharmacy from serving as a manager, administrator, owner,
26 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
27 Number PHY 44487 is placed on probation or until Pharmacy Permit Number PHY 44487 is
28 reinstated if the Pharmacy Permit is revoked;

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

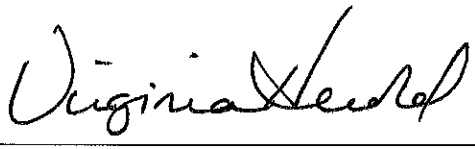
4. Prohibiting Qui Van Ly from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if either Pharmacy Permit Number PHY 44487 or Pharmacist License Number RPH 41386 is placed on probation;

5. Prohibiting Qui Van Ly from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee if either Pharmacy Permit Number PHY 44487 or Pharmacist License Number RPH 41386 is revoked, until Pharmacy Permit Number PHY 44487 or Pharmacist License Number RPH 41386 is reinstated;

6. Ordering Fresno Pharmacy and Qui Van Ly to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

7. Taking such other and further action as deemed necessary and proper.

DATED: 7/8/16



VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2016100089
12097582